

THE OFFICE ACTION

In the Office Action issued on April 13, 2007, the Examiner rejected claims 1-6, 8-13 and 17 under 35 U.S.C. §103(a) as being unpatentable over Wakeman in view of Berger (US Patent 4,574,084). The Examiner also rejected claims 1-19 under 35 U.S.C. §103(a) as being unpatentable over Vandevelde in view of Berger. The Examiner also rejected claims 1-19 under 35 U.S.C. §103(a) as being unpatentable over Harwardt in view of Berger.

REMARKS

Applicants have carefully considered the Office Action issued on April 13, 2007. Applicants respectfully request reconsideration of the application in light of the following comments.

Wakeman in view of Berger

Wakeman is directed to the preparation of microbiologically active compounds by the reaction of certain quaternary ammonium hydroxides or salts with arylsulfonamides or their alkali-metal salts (see Column 1, Lines 11 to 14). Consequently, Wakeman is not directed to arylsulfonamides as such but to the reaction products of arylsulfonamides with quaternary ammonium hydroxides.

Further, contrary to the Examiner's contention, Wakeman is **not** directed to a pharmaceutical composition that can treat skin diseases. In fact, Wakeman is directed to an **antiseptic** composition that is to be used for an antiseptic treatment of items like fabric, canvas, ropes, textiles, awnings, sails, tenting and other woven and non-woven reticulated materials (see Column 3, Lines 41 to 46). Among the many uses mentioned in Wakeman for the compositions is that of a topical antiseptic, an antidandruff agent or a disinfection agent for hair and gut of man and beast. However, it is to be emphasized that, contrary to the opinion of the Examiner, these uses are not directed to the treatment of skin diseases. In Wakeman, the function of the compounds is defined as "microbiological activity" as determined by the Standard Tube Dilution Test, i.e. bacteriostatic function and bactericidal function.

Applicants respectfully submit that bacteriostatic and bactericidal functions, as

performed by an agricultural chemical, are substantially different from therapeutic function, as performed by a pharmaceutical treating a skin disease. Please see Wakeman, Lines 25-31 of Column 2. The treatment of skin diseases is not mentioned at all in Wakeman. In fact, Wakeman is directed to a composition that can be used as a disinfection agent for the various items including, among many others, skin or hair. Nevertheless, these uses are directed to the disinfection of skin or hair and not to the treatment of skin diseases. Consequently, Wakeman cannot render obvious the subject-matter of the claims of the present invention.

Furthermore, Berger does not provide the skilled artisan with any suggestion that could lead him to the present invention. Berger is directed to:

“...a process for the preparation of a stabilized, modified, aqueous chlorite solution with a content of a peroxy compound, the chlorite solution obtained by this process and the multiple possible uses thereof as a biocide” (see Column 1, Lines 8 to 12).

Consequently, Berger relates to a disinfection agent comprising a chlorite solution and a peroxy compound.

The mechanism of the biocide activity of said composition is explained later in Berger wherein it is stated:

“...., therefore for stabilizing the chlorite in the aqueous solution, peroxy compounds are used which stabilize on a long-term basis the oxidation system based on the chlorite while retaining the sought oxidative activity” (see Column 2, Lines 31 to 35).

Consequently, the biocide activity of the composition disclosed in Berger is based on strong oxidative activity. This makes the composition disclosed in Berger fundamentally different from the tosylchloramides employed in the method according to the present invention.

It is therefore not apparent how the skilled artisan would combine the teaching of Wakeman with that of Berger, because Wakeman is directed to the reaction products of quaternary ammonium hydroxide with arylsulfonamides and Berger is directed to strongly oxidative compositions of chlorites and oxy-compounds. Further, even if the skilled artisan would make such a combination, he would still not arrive at the teaching

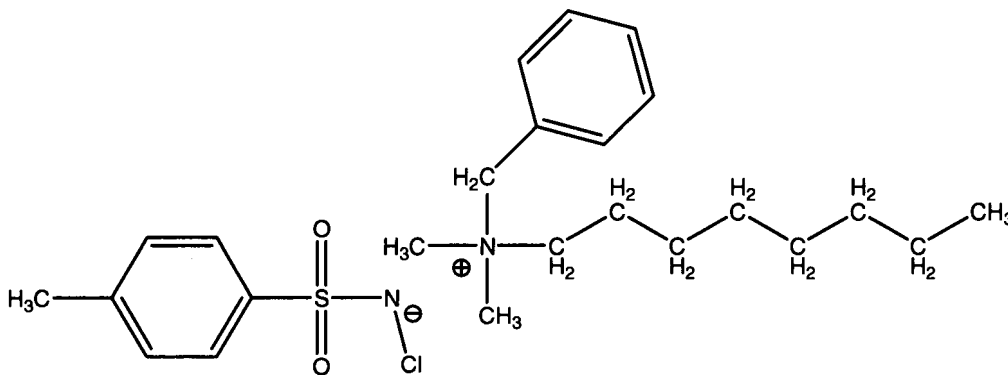
of the present invention, since there is no indication in Berger that the activities of the chlorite/peroxy compositions described therein could be considered for tosylchloramides.

Therefore, the combination of Wakeman and Berger cannot render obvious the subject-matter of the present invention.

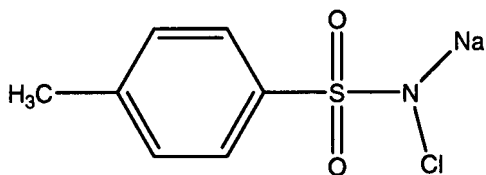
To support the combination of Wakeman with Burger, in the Office Action, the Examiner points out that:

“One having ordinary skill in the art at the time the invention was made would have been motivated to employ tosylchloramide(s) and their salts in treating particular skin diseases such as psoriasis and herpes because: (1) Wakeman teach antimicrobial, disinfectant, and biocidal pharmaceutical compositions comprising tosylchloramide(s) and their salts for treating skin diseases; (2) Berger teaches that common skin diseases, such as psoriasis and herpes, are caused by bacteria, viruses, and fungi; and (3) Berger also give the general teaching that such skin diseases can be treated with biocidal compositions that are used for disinfection. Therefore, one of ordinary skill in the art would have had a reasonable expectation of success in treating skin diseases such as psoriasis and herpes with an antimicrobial composition comprising tosylchloramide(s) as disclosed by Wakeman because of the beneficial therapeutic effects of tosylchloramide(s) on killing and destroying harmful microorganisms that cause such skin diseases”.

The Examiner's reasoning is without merit because the compound in Applicant's Claim 1 is structurally distinct from that of Wakeman, as shown below:



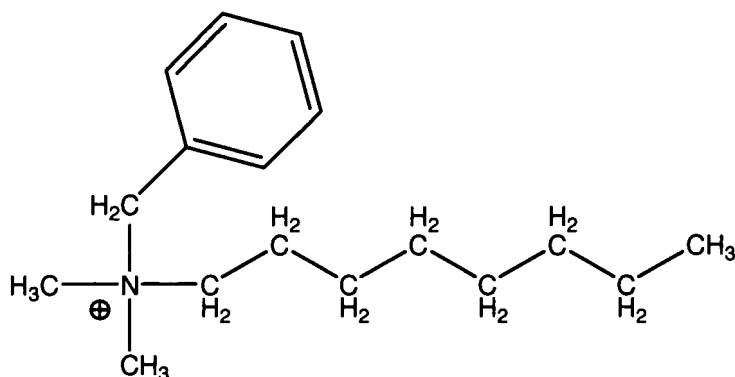
The Wakeman compound based on its Claim 10 in view of its Lines 1-5, Column 2



An example defined by Applicant's Claim 1

Applicant respectfully submits that the two structures are not similar. As such, a prima facie case on obviousness has not been established. Moreover, there is no basis that "similar structures give similar functions", particularly where we are not dealing with "similar" structures.

Secondly, Even assuming the above two compounds are similar in terms of structural chemistry (*or in vacuum*), Wakeman strongly suggests that the quaternary ammonium, i.e. the structural moiety unique to the invention, plays a decisive role for the intended function.



Wakeman requires that his quaternary ammonium moiety must in the first place be good against both *Staphylococcus aureus* and *Salmonella typhosa*, so as to achieve the intended function of his invention, which is also microbiological activity against *Staphylococcus aureus* and *Salmonella typhosa*. Please see Lines 25-31 of Column 2; Claim 1; Lines 16-25 of Column 4; Example IV; Example V; and Example VI.

The Examiner now states that Berger allegedly proves that a compound that generally prohibits or kills microorganism X can be used as a pharmaceutical that cures diseases caused by microorganism X. However, Berger itself rebuts this reasoning. Berger teaches that the fact that a compound can generally prohibit or kill microorganism X is NOT enough to establish that the compound can be used "in

pharmaceutical field". Please see Lines 18-25, Column 8. Burger warns a skilled artisan that other factors must also be considered, such as the pharmaceutical's compatibility with skin, among others. Please see Lines 18-25, Column 8. Similarly, not all chemical disinfectants have appropriate pharmaceutical properties. Inventive selection is needed. In *Perricone v. Medicis Pharm. Corp.*, 432 F.3d 1368, (Fed. Cir. 2005). The Court held that claims for a method of treating sunburned skin were not inherently anticipated by prior art directed to cosmetic compositions containing the same compounds for topical application, since the disclosed use of the prior art lotion did not suggest application of the lotion to skin sunburn. "Skin sunburn is not analogous to skin surfaces generally. Thus, there is an important distinction between topical application to skin for the purpose of avoiding sunburn, and the much narrower topical application to skin sunburn."

In contrast, Applicant's invention exhibits its suitability as a pharmaceutical, such as "practically free from side effect"; (Line 23, Page 2) 13 out of 15 patients' reported that the invention exhibits good to excellent effect and overall result; (Pages 13-14) and "raise no inherent concern regarding compatibility upon direct contact with the skin and potential sensibilisation, such as for example the local application in appropriate combination with an ointment". (Lines 14-16, Page 8).

Vandeveldt in view of Berger

Vandeveldt is directed to "an agent which acts against retrovirus group viruses, in particular Human Immunodeficiency Virus (HIV)," (Please see abstract and Page 1, Lines 3 to 6).

It is to be emphasized that the Human Immunodeficiency Virus does not cause a disease of the skin and in particular does not cause a disease of the skin selected from the skin diseases mentioned in claim 1 of the present invention.

Consequently, Vandeveldt cannot give the skilled artisan any incentive to consider the method according to the present invention. Further, a combination of Vandeveldt with Berger cannot render obvious the subject-matter of the present invention, since, as outlined above, Berger is concerned with biocide compositions totally different from the compounds used according to the present invention.

Furthermore, as detailed above, none of structural and functional aspects of Vandavelde can be used as a basis to reject Applicant's claims. Moreover, Vandavelde is explicitly restricted to the use of chlorinated organic compounds, which stably and lastingly release chlorine, against retrovirus group viruses, in particular Human Immunodeficiency Virus (HIV) on and/or in inanimate objects, rather than human skin.

Harwardt in view of Berger

Turning now to the rejection based on Harwardt in view of Berger, Applicants note that Harwardt is directed to an antimicrobial combination of actives, which is defined in that document as follows: "Die Erfindung betrifft eine antimikrobielle Wirkstoffkombination auf der Basis sauerstoffabspaltenden Verbindungen zur Antiseptik und Desinfektion von Haut, Schleimhaut und Wunde in und am tierischen und menschlichen Organismus."

- in English -

"The invention is directed to an antimicrobial combination of actives on the basis of oxygen cleaving compounds for antiseptic and disinfection of skin, mucous membrane and wounds in and on the animal or human organism".

Consequently, Harwardt is also directed to oxidative disinfection agents, which are totally different from use of the tosylchloramides according to the present invention.

The fact that beside the oxygen cleaving compounds which form the basis of the compositions disclosed in Harwardt, also chlorine cleaving compounds can be used in admixture with the oxygen cleaving compounds, does not change the fact that Hepper is directed to compositions that contain oxygen cleaving compounds as the basis of the composition.

Consequently, Harwardt cannot render obvious the subject-matter of the claims of the present invention. Further, a combination of Harwardt with Berger cannot give the skilled artisan any incentive to consider the subject-matter of the present invention, because Berger itself is also directed to an oxidative disinfection composition (see above).

None of the structural and functional aspects of Harwardt can be used as ground

to reject Applicant's claims, since Harwardt is directed to an antimicrobial combination on the basis of compounds, which are able to split off oxygen. The basis of Harwardt is that a special combination of chemical compounds as disinfectant is obtained which is highly active as disinfectant at the same time well tolerated on the skin, rather than compatibility with skin in the context of medicine.

CONCLUSION


For the reasons detailed above, it is respectfully submitted all claims remaining in the application (Claims 1-19) are now in condition for allowance. Applicants respectfully request early notification of such allowance. Should any issues remain unresolved, the Examiner is encouraged to contact the undersigned to attempt to resolve any such issues.

If any fee is due in conjunction with the filing of this response, Applicants authorize deduction of that fee from Deposit Account 06-0308.

Respectfully submitted,

FAY SHARPE LLP

October 15, 1987
Date



Scott A. McCollister
Reg. No. 33,961
1100 Superior Avenue, Seventh Floor
Cleveland, OH 44114-2579
216-861-5582